REMARKS

In response to the Office Action mailed on June 14, 2005, Applicants amended claims 2, 41, and 46, and cancelled claims 32-40. Claims 1-9, 11-30, and 41-58 are presented for examination.

Double Patenting

The Examiner provisionally rejected claims 1-30 under the doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 19-33 of co-pending U.S. Patent Application No. 10/215,594. Applicants request that this provisional rejection be held in abeyance.[1]

Claim Rejections – 35 U.S.C. § 112

The Examiner rejected claims 1-9, 11-30, and 32-58 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. According to the Examiner, the specification does not enable the formation of a particle with the claimed pore density relationship.

Claims 20, 21, 30, and 48-58, while encompassing particles that may have various pore density relationships, do not include any limitations that specify pore density. However, claims 1-9, 11-19, 22-29, and 41-47 do include limitations that specify pore density.

Applicants' specification provides ample disclosure of methods that can be used to form particles covered claims 1-9, 11-30, and 41-58. For example, pages 11-18 and FIGS. 3A, 3B, and 4 of Applicants' specification describe a system including a drop generator that can be used to make particles, such as particles that include polyvinyl alcohol. The drop generator is used to form drops of a solution, which drops are then processed to form particles. (See, e.g., Application, pages 11-18.)

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[1] In making the double patenting rejection, the Examiner asserted that the rejection cannot be overcome until a proper terminal disclaimer is submitted. (June 14, 2005 Office Action, page 2.) Applicants do not concede that this is correct. (See, e.g., M.P.E.P. § 804 (8th ed., Rev. 2, May 2004).)

Applicants' specification describes this particle formation process in detail. To begin with, Applicants' specification provides numerous examples of materials, such as base polymers, gelling precursors, gelling agents, and cross-linking agents, that can be used in this particle formation process, as well as weight percent ranges for these materials. (See, e.g., id., pages 11-12 and 15-17.) Applicants' specification also provides a detailed explanation of, for example, the formation of mixtures that can be used in the particle formation process (see, e.g., id., page 12), as well as the pressures, temperatures, and flow rates that can be used in the particle formation process (see, e.g., id., pages 12-14).

Additionally, Applicants' specification describes how to control the porosity gradient in particles that are formed. For example, Applicants' specification includes the following description regarding controlling the porosity gradient:

> The concentration of the gelling agent [used to gel material in the drops] can affect pore formation in the particle, thereby controlling the porosity gradient in the particle. Adding non-gelling ions (e.g., sodium) to the gelling solution can reduce the porosity gradient, resulting in a more uniform intermediate porosity throughout the particle. In embodiments, the gelling agent is, for example, from about 0.01 weight percent to about 10 weight percent (e.g., from about one weight percent to about five weight percent, about two weight percent) in deionized water. (Id., page 16.)

Furthermore, in addition to describing how to form particles of a certain size (see, e.g., id., page 15), Applicants' specification clearly describes how to select particles within certain size ranges, once the particles have been formed. As disclosed in Applicants' specification, after the particles have been formed, they are filtered through a filter to remove residual debris. (Id., page 18.) The particles can be filtered using sieves that are selected to allow passage of particles of certain sizes, and to collect particles of other sizes. (See id.) For example, particles having a diameter of from about 100 microns to about 300 microns can be filtered through a sieve of about 710 microns and then a sieve of about 300 microns, and can be collected on a sieve of about 20 microns. (Id.)

Applicants' specification also includes several examples of particles that were made. (See id., pages 21-26.) These examples include detailed information about how the particles

were made, as well as information about the characteristics of the particles. For example, the particles prepared in Example 2 of Applicants' specification were prepared from an aqueous solution containing 7.06 weight percent polyvinyl alcohol and 1.76 weight percent sodium alginate. (See id., pages 23-24.) The particles were prepared by heating the solution to about 121°C, feeding the solution into an Inotech Encapsulator unit IE-50R/NS drop generator, forming drops using the drop generator, and contacting the drops first with a solution including two weight percent calcium chloride and then with a solution including four weight percent formaldehyde and 20 weight percent sulfuric acid. (See id.) As described in Applicants' specification, the resulting particles had a size range of 100-300 microns or 300-500 microns, depending on the nozzle diameter, frequency, pressure, and flow rate (provided in Table II) that were used in forming the particles. (See id., page 24.)

In view of the foregoing, Applicants request reconsideration and withdrawal of the rejection of claims 1-9, 11-30, and 41-58.[2]

The Examiner rejected claims 2, 4, and 32-40 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement because a statement in the specification is in direct contrast with the pore structure required in claims 2, 4, and 32-40. Applicants amended claim 2 to obviate the rejection of this claim, and Applicants cancelled claims 32-40. Regarding claim 4, a written description of the subject matter of claim 4 is included, for example, on page 7 of Applicants' specification, which states, "Pores near the center of the particle are relatively large, and pores near the surface of the particle are relatively small." Applicants therefore request reconsideration and withdrawal of this rejection.

The Examiner rejected claims 2, 4, and 32-40 under 35 U.S.C. § 112, second paragraph, as failing to set forth the subject matter which Applicants regard as their invention. More specifically, the Examiner asserted that claims 2, 4, and 32-40 require that the pore density at an interior region of the particle be greater than the pore density at a surface region of the particle, and noted that this is inconsistent with Applicants' specification. Applicants cancelled claims 32-40 and amended claim 2 to obviate the rejection of claim 2. Claim 4 encompasses particles

[2] Applicants note that claims 1-9, 11-30, and 41-58 are directed to particles that are not limited by the processes by which they are made.

that may have various pore density relationships, and does not specify pore density. In view of this, and in view of the amendment to claim 2, Applicants believe that the rejection of claims 2 and 4 should be reconsidered and withdrawn.

Claim Rejections – 35 U.S.C. § 102

The Examiner rejected claims 1, 3-9, 13, 14, 18-22, 25-30, 41-45, and 48-58 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,888,930 (Smith).

Claims 1, 3-9, 13, 14, 18, 19, 20, 21, 22, 25-30, and 48-58 cover a particle or particles including a polyvinyl alcohol. But Smith fails to disclose a particle or particles including a polyvinyl alcohol.

Smith discloses "asymmetric microporous beads" that have a "continuous gradation of pore sizes". (Smith, col. 2, lines 21-31.) Smith notes that the beads can be formed of polymers, and states:

> Polymers useful for preparation of the beads of the present invention include polycarbonates, polysulfones, polyamides, polyurethanes, acrylic resins, polyvinyl chloride, polyvinyl fluoride, polyacrylonitrile, polystyrene, polyolefins, polyvinylidene chloride, polyvinylidene fluoride, polyethyleneterephthalate, polybutyleneterephthalate, cellulose acetate and other cellulosic esters, polyimides, polyacetals, polyvinylacetate, polyphenyleneoxide, polyetherimides, ethylenevinyl-alcohols, and derivatives and copolymers of the above. Useful polymers must be soluble in a suitable solvent and insoluble in a liquid that is miscible with the solvent. (Id., col. 2, line 57 — col. 3, line 1.)

While Smith discloses that the beads can include "ethylenevinyl-alcohols, and derivatives and copolymers of [ethylenevinyl-alcohols]", Applicants do not concede that this group of materials includes polyvinyl alcohols. And even if it did include polyvinyl alcohols, Smith's disclosure of this group of materials is not an anticipatory disclosure of polyvinyl alcohols. In In re Meyer, the Court of Customs and Patent Appeals explained that:

> The genus, "alkaline chlorine or bromine solution," does not identically disclose or describe, within the meaning of § 102, the species alkali metal hypochlorite,

> since the genus would include an untold number of species. (In re Meyer, 599 F.2d 1026, 1031 (C.C.P.A. 1979))

Similarly, a disclosure of a broad genus potentially including innumerable species of ethylenevinyl-alcohols, ethylenevinyl-alcohol derivatives, and ethylenevinyl-alcohol copolymers is not an anticipatory disclosure of a polyvinyl alcohol. Accordingly, Smith fails to anticipate claims 1, 3-9, 13, 14, 18, 19, 20, 21, 22, 25-30, and 48-58, and Applicants request that the rejection of these claims be reconsidered and withdrawn.

As amended, claims 41-45 require a particle including a polysaccharide and having a diameter of about 500 microns or less. Smith discloses microporous beads that include one or more bead cores including microcrystalline cellulose, and that are two to three millimeters in diameter. (See Smith, col. 10, line 60 — col. 11, line 6.) Smith fails to disclose a particle including a polysaccharide and having a diameter of about 500 microns or less. Accordingly, Smith does not anticipate claims 41-45, and Applicants request that the rejection of claims 41-45 be withdrawn.

The Examiner rejected claims 41-46 as being anticipated by DE 100 26 620 (Quelle).

As amended, claims 41-46 cover a particle having an interior region defining pores and a surface region defining pores. The particle has a first density of pores in the interior region and a second density of pores at the surface region. The first density is different from the second density.

Quelle discloses porous particles and microspheres. (See Quelle, Abstract.) The particles can have a cavity and a shell that is either porous or non-porous. (See id., ¶0017.) As Quelle explains,

> Through the use of inner cavities, with or without recesses on the outer surface of the particles, or microspheres, with or without connecting channels through the nonporous or even porous shell, the product invention constitutes a suitable depot or transport medium . . . for . . . medical . . . applications. (Id., ¶0010.)

While Quelle discloses porous particles, Quelle does not disclose that his porous particles can have two porous regions with different pore densities. Accordingly, Quelle does not disclose

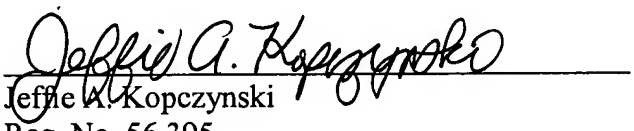
particles covered by claims 41-46. Applicants therefore request that the rejection of these claims be withdrawn.

Applicants believe that claims 1-9, 11-30, and 41-58 are in condition for allowance, which action is requested.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: September 9, 2005



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